

# PATENT COOPERATION TREATY

from the:

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Baldwin Shelston Waters  
PO Box 852  
Wellington 6001  
NEW ZEALAND

BSW SYDNEY

1 - MAR 2004

Mail  
No:

273909

Date of mailing  
(day/month/year)

20 FEB 2004

Applicant's or agent's file reference  
503958/142

REPLY DUE

within **TWO MONTHS**  
from the above date of mailing

International Application No.

PCT/NZ03/00111

International Filing Date (day/month/year)

4 June 2003

Priority Date (day/month/year)

4 June 2002

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. <sup>7</sup> C07K19/00, C07K14/00, C07K 014/315, C07K 016/12; A61K 035/74, A61K39/00, A61K 039/09, A61K39/39; C12N 001/20, C12N15/31; C07H 019/00; C12Q 001/68

Applicant

AUCKLAND UNISERVICES LIMITED et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:  
4 October 2004

4. The applicant is hereby **invited to reply** to this opinion.

**When?** See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. **If no response is filed by 1 month before the Final Date**, the international preliminary examination report will be established on the basis of this opinion.

Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6.

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaaustralia.gov.au  
Facsimile No. (02) 6285 3929

Authorized Officer

D.A. LALLY

Telephone No. (02) 6283 2533

# WRITTEN OPINION

International application No.

PCT/NZ03/00111

## I. Basis of the opinion

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

### 5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1 to 24	YES
	Claims nil	NO
Inventive step (IS)	Claims 1 to 24	YES
	Claims nil	NO
Industrial applicability (IA)	Claims 1 to 24	YES
	Claims nil	NO

**2. Citations and explanations**

- **Document 1:** Fraser, J.D. *et al*: Journal of Immunology, (1 September 2002) 169 (5) 2561-9. "The bacterial superantigen streptococcal mitogenic exotoxin Z is the major immunoactive agent of *Streptococcus pyogenes*".
- **Document 2:** Proft, T. *et al*: Journal of Experimental Medicine, (15 May 2000) 191 (10) 1765-76. "The Streptococcal Superantigen SMEZ Exhibits Wide Allelic Variation, Mosaic Structure, and Significant Antigenic Variation".
- **Document 3:** Arcus, V.L. *et al*: Journal of Molecular Biology, (26 May 2000) 299 (1) 157-68. "Conservation and Variation in Superantigen Structure and Activity Highlighted by the Three dimensional Structures of Two New Superantigens from *Streptococcus pyogenes*".
- **Document 4:** Proft, T. *et al*: Journal of Experimental Medicine, (4 January 1999) 189 (1) 89-101. "Identification and Characterisation of Novel Superantigens from *Streptococcus pyogenes*".
- **Document 5:** WO 2002/45739 A1 (Auckland Uniservices Limited), 13 June 2002.

None of Documents 1 to 5 either read alone or in combination with any other document teaches nor suggests any aspect of the invention claimed, rendering all claims both novel and inventive.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The term "does not include a fully functional T-cell receptor binding site" is not properly supported by the description.

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 503958/142	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/NZ2003/000111</b>	International Filing Date (day/month/year) 4 June 2003	Priority Date (day/month/year) 4 June 2002
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. <sup>7</sup> C07K19/00, C07K14/00, C07K 014/315, C07K 016/12; A61K 035/74, A61K39/00, A61K 039/09, A61K39/39; C12N 001/20, C12N15/31; C07H 019/00; C12Q 001/68</b>		
Applicant  <b>AUCKLAND UNISERVICES LIMITED et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 7 November 2003	Date of completion of the report 20 September 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>D.A. LALLY</b> Telephone No. (02) 6283 2533

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description,      pages      , as originally filed,  
                                 pages      , filed with the demand,  
                                 pages      , received on      with the letter of
- ☐ the claims,      pages      , as originally filed,  
                                 pages      , as amended (together with any statement) under Article 19,  
                                 pages      , filed with the demand,  
                                 pages      , received on      with the letter of
- ☐ the drawings,      pages      , as originally filed,  
                                 pages      , filed with the demand,  
                                 pages      , received on      with the letter of
- ☐ the sequence listing part of the description:  
                                 pages      , as originally filed  
                                 pages      , filed with the demand  
                                 pages      , received on      with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description,      pages
- ☐ the claims,      Nos.
- ☐ the drawings,      sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/NZ2003/000111

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1 to 24	YES
	Claims nil	NO
Inventive step (IS)	Claims 1 to 24	YES
	Claims nil	NO
Industrial applicability (IA)	Claims 1 to 24	YES
	Claims nil	NO

## 2. Citations and explanations (Rule 70.7)

- **Document 1:** Fraser, J.D. *et al*: Journal of Immunology, (1 September 2002) 169 (5) 2561-9. "The bacterial superantigen streptococcal mitogenic exotoxin Z is the major immunoactive agent of *Streptococcus pyogenes*".
- **Document 2:** Proft, T. *et al*: Journal of Experimental Medicine, (15 May 2000) 191 (10) 1765-76. "The Streptococcal Superantigen SMEZ Exhibits Wide Allelic Variation, Mosaic Structure, and Significant Antigenic Variation".
- **Document 3:** Arcus, V.L. *et al*: Journal of Molecular Biology, (26 May 2000) 299 (1) 157-68. "Conservation and Variation in Superantigen Structure and Activity Highlighted by the Three dimensional Structures of Two New Superantigens from *Streptococcus pyogenes*".
- **Document 4:** Proft, T. *et al*: Journal of Experimental Medicine, (4 January 1999) 189 (1) 89-101. "Identification and Characterisation of Novel Superantigens from *Streptococcus pyogenes*".
- **Document 5:** WO 02/45739 A1 (Auckland Uniservices Limited), 13 June 2002.

None of Documents 1 to 5 either read alone or in combination with any other document teaches nor suggests any aspect of the invention claimed, rendering all claims both novel and inventive.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The term "does not include a fully functional T-cell receptor binding site" is not properly supported by the description.